REMARKS

Claims 1-8 are pending in the subject application. By this amendment, applicants have amended claims 1, 2 and 3. Accordingly, upon entry of this Amendment, claims 1-8, as amended, will be pending and under examination. Applicants maintain that the amendments to the specification and claims raise no issue of new matter and respectfully request entry of this Amendment.

Support for the amendment to the specification to correct a typographical error in the spelling of the author name to "Petersen" is supported by the full citation of the article listed in the specification, as originally-filed, on page 1, line 10. A copy of the Petersen et al. 2001 article is attached hereto.

Support for the amendments to the claim 1 may be found *inter alia* in the specification, as originally-filed, on page 1, line 10; and page 6, lines 1-5. Support for the amendments to the claim 2 may be found *inter alia* in the specification, as originally-filed, on page 2, line 22 through page 7, line 12; and page 10, lines 4-18. Support for the amendments to the claim 3 may be found *inter alia* in the specification, as originally-filed, on page 1, line 11.

Accordingly, applicants respectfully request that the Amendment be entered.

Rejection Under 35 U.S.C. §103(a)

On page 2 of the October 6, 2006 Office Action, the Examiner rejected claims 1-8 under 35 U.S.C. 103(a) as allegedly being unpatentable over Seredenin et al. (US 5,430,930). The Examiner alleges that Seredenin et al. (US 5,430,930) teach that the present compounds are known, namely, N-acyl-(Pro-Gly)-prolyldipeptides, including the preferred embodiment in present claim 8 for "improvement of cognitive function damaged by [ ] aging" (col. 3, lines 15-25). Seredenin et al. was issued in 1995, before the label MCI was even

created/defined (it is assumed by the Examiner after a review of the art). The Examiner points out that since the present claims are described as a symptom of MCI, the Seredenin et al. reference is applied under 103 as opposed to 102.

The Examiner further alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat a symptom of MCI, in Seredenin et al., because Seredenin et al. advantageously teach that the present compounds are known for "improvement of cognitive function damaged by [ ] aging" (col. 3, lines 15-25). Seredenin's description of "improvement of cognitive function damaged by [ ] aging", at least in theory, partially meets the definition for the newly labeled disorder MCI.

Applicant respectfully traverses the Examiner's rejection for the following reasons. Seredenin et al. teach treatment of impaired cognition associated with normal aging. Seredenin et al. neither teach nor suggest a pathologic condition, such as MCI.

Page 1987, paragraph 3 of Petersen et al (2001) explains:

> Previous attempts at characterizing cognitive changes intrinsic to normal aging have produced several terms, such as benign senescent forgetfulness, age-associated memory impairment, and age-associated cognitive decline. These terms are generally meant to reflect the extremes of normal aging rather than to describe a precursor of pathologic aging. While investigations of these concepts demonstrate dementia conversion rates that are not different from those of healthy subjects, others have indicated an increased conversion rate. Subjects with MCI have a condition that is different from normal aging, and longitudinal outcome results indicate that they are likely to progress to AD at an accelerated rate.

The state of the art, at the time the subject application was filed, indicated that MCI could be distinguished from the parameters associated with normal aging by neuropsychological assessments. These assessments were already being made by clinicians to clinically diagnose MCI. (See, for example, Petersen, R.C. et al. *Arch. Neurol.* 56: 303-308 (1999), a copy of which is attached hereto; for further review, see also Petersen, R.C. et al. *JAMA.*

273: 1274-1278 (1995).) Examples of such neuropsychological assessments are described in the instant application as filed on page 4, line 5 through page 5, line 20. Furthermore, one of ordinary skill in the art understood that symptoms of MCI are indicative of a pathological state that is likely to progress to AD.

In order to test for cognitive enhancement of the subject compounds, Seredenin et al. provides animal (rat) models that are altered by prenatal alcoholization, frontal lobectomy, electric shock, or otherwise subjected to negative learning. The Seredenin cognitive tests do not mimic or suggest symptoms of MCI. As such, Seredenin et al. do not suggest the unexpected properties of the identified compounds to treat MCI. Even if it could be said that Seredenin et al. suggested that cognitive function could be improved by administration of the subject compounds, there is little, if any, motivation in that suggestion to treat a subset patient population of Seredenin for cognitive impairment associated with *pathologic aging*. Nor is their any motivation to use the subject compounds to treat a subset patient population of Seredenin for cognitive impairment *that is likely to progress to AD*.

Because Seredenin et al. provide no suggestion or motivation to treat patients with the subject compounds for MCI, Applicant respectfully requests that the rejection be withdrawn.

Rejection On The Ground of Nonstatutory Provisional Obvious-type Double Patenting

On page 4 of the October 6, 2006 Office Action, the Examiner alleges that claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 11/136,272. Although the conflicting claims are not identical, The Examiner alleges that the claims are not patenably distinct from each other.

In response, without conceding the correctness of the Examiner's position, Applicant will consider filing a Terminal Disclaimer or claim amendments upon the indication of allowable subject matter.

Rejection Under 35 USC § 112, First Paragraph

On page 4 of the October 6, 2006 Office Action, the Examiner rejected claims 1-8 under 35 USC 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner alleges that the claims(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention. The Examiner alleges that the subject application is not enabled for treating a symptom of MCI using the N-acyl-(Pro-Gly)-prolyldipeptides.

Applicant notes that the burden of showing non-compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, rests upon the U.S. Patent and Trademark Office in making and maintaining a rejection. See, e.g., *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (See also MPEP 2164.04.) In the rejection, the Examiner states that the references cited in the specification do not describe whether MCI and it's symptoms are completely defined under the medical model and, that even if a definition and symptomology have risen to the level of recognition by the medical practitioner, whether MCI is even capable of treatment.

Thus, the rejection casts doubt that *any* compounds are capable of treating MCI. However, the rejection provides no further evidence or justification of the allegation with respect to the state of the art. Without some articulated rationale to support why the distinction alleged in the rejection is existent, meaningful and relevant to the analysis of the

enablement requirement, the alleged distinction of whether "MCI is even capable of treament" stands as a naked assertion rather than evidence or reasons why the disclosure does not enable a person skilled in the art to practice the invention without undue experimentation. Accordingly, Applicants respectfully submit that the rejection does not meet the well-established burden of showing non-compliance with section 112 as set forth in *In re Wright.* (see also MPEP 2164.01).

In any event, Applicants note that it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003). See MPEP §2164.

Further, Applicant respectfully submits that the rejection is not consistent with the knowledge of the skilled artisan. One of ordinary skill in the art recognizes that AD can be treated with several well-known compounds, e.g. cholinesterase inhibitors such as tacrine, donepezil and rivastigmine. Given the teachings of the subject application, MCI can be assessed by well-known neuropsychological tests to determine patients in need of treatment prior to its progression to AD. Thus one skilled in the art recognizes that treatments for MCI are also feasible. US 2002/0187977, published December 12, 2002 (a copy of which is attached hereto) indicates that measured improvement in one or more cognitive tests such as MMSE and OCS are capable with the administration of N-phenacetyl-L-prolylglycine ethyl ester; Froestl et al. 2004 (a copy of which is also attached hereto) indicate that $GABA_B$ antagonists are useful for the treatment of MCI; therefore, it is understood that MCI is capable of treatment.

Thus, it cannot be said that the teachings of Applicant's specification are contrary to generically accepted principles in such a way to case doubt as to the operability of Applicant's invention. Still, the state of the art underlines the fact that the assertions of the

rejection fail to meet burden of establishing that Applicants' specification is not compliant with 35 U.S.C. 112. Withdrawal of this rejection is therefore earnestly solicited.

Rejection Under 35 USC § 112, Second Paragraph

On page 8 of the October 6, 2006 Office Action, the Examiner rejected claim 2 under 35 U.S.C. 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In an attempt to advance the prosecution of the subject application, but without conceding the correctness of the Examiner's position, Applicant has amended claim 2 to recite "delayed recall tasks in response to verbal and nonverbal stimuli". Claim 2 is further amended to recite the phrase "single cognitive domain other than the cognitive domain(s) responsible for memory". Applicant maintains that claim 2 clearly points out the subject matter being claimed.

Accordingly, withdrawal of this rejection is earnestly solicited.

Claim Objections

On page 8 of the October 6, 2006 Office Action, the Examiner objected to claim 1 because allegedly MCI should be expanded to its full phraseology for clarity and understanding. The Examiner also objected to claim 2 for consistent language therein.

Applicant thanks the Examiner for such suggestions in claim language. Applicant has amended claims 1 and 2 accordingly, and respectfully requests withdrawal of the claim objections.

Specification Observation

On page 9 of the October 6, 2006 Office Action, the Examiner points out a spelling error on

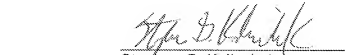
page 1, paragraph 1 of the specification. The author name "Peterson" should be "Petersen". Applicant has made the appropriate amendment to the specification and has attached a copy of the Petersen et al. reference for clarification.

In light of the amendments and remarks made hereinabove, Applicant respectfully requests that the Examiner withdraw the various rejections and earnestly solicit allowance of currently pending claims 1-8.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone the number provided below.

No fee, other than the fee for the three-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 50-3201.

Respectfully submitted,



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